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2d Session

HOUSE OF REPRESENTATIVES

REPORT
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COMMISSIONER OF FOOD AND DRUGS

AUGUST 12, 1986.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

REPORT

[To accompany H.R. 4754]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4754) to amend the Federal Food, Drug, and Cosmetic Act to require the appointment of the Commissioner of Food and Drugs to be subject to Senate confirmation, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PURPOSE AND SUMMARY

The purpose of H.R. 4754 is to provide for Senate confirmation of the Commissioner of the Food and Drug Administration. The legislation requires that the Commissioner of the Food and Drug Administration be appointed by the President and be confirmed by the Senate.

BACKGROUND AND NEED FOR THE LEGISLATION

The Food and Drug Administration (FDA) is an agency of the Department of Health and Human Services. The FDA is headed by a Commissioner. When it comes to protecting the public health, there is no more important position than Commissioner of the FDA. The responsibilities of the FDA are great.

The Food and Drug Administration represents the only line of defense between the public and unhealthy foods, unsafe drugs, ineffective medical devices or unfounded health claims.

Ironically, the FDA Commissioner is alone among major regulatory agency heads who are not subject to Presidential appointment

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or Senate confirmation. The head of every major Federal health and safety agency is currently subject to Presidential appointment and Senate confirmation. The list includes the: Federal Aviation Administration, Environmental Protection Agency, Occupational Health And Safety Administration, National Highway Traffic And Safety Administration, Consumer Product Safety Commission, and Nuclear Regulatory Commission.

In addition, other offices within the Department of Health and Human Services require Presidential appointment and Senate confirmation. In addition to the Secretary, these offices include: the Surgeon General, the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse and Mental Health Administration and the Director of the National Cancer Institute.

The Committee believes that Senate confirmation is a constructive and worthwhile process. It is a procedure that should apply to persons appointed to serve as Commissioner of the Food and Drug Administration.

HEARINGS

The Committee's Subcommittee on Health and the Environment held one day of hearings on H.R. 3909, on March 6, 1986. Testimony was received from two witnesses; Senator Albert Gore (D. Tenn) and Ian Donald MacDonald, Acting Assistant Secretary for Health, Department of Health and Human Services.

COMMITTEE CONSIDERATION

On April 23, 1986, the Subcommittee on Health and the Environment met in open session and ordered reported as a clean bill, H.R. 3909, as amended, by unanimous voice vote, a quorum being present. On May 6, 1986, legislation (H.R. 4754) reflecting the subcommittee's action was introduced by Mr. Waxman. On July 29, 1986, the Committee met in open session and ordered reported the bill H.R. 4754, without amendment, by voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, no oversight findings or recommendations have been made by the Committee.

COMMITTEE ON GOVERNMENT OPERATIONS

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

COMMITTEE COST ESTIMATE

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the Committee believes the bill will not require additional appropriations.

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CONGRESSIONAL BUDGET OFFICE ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, August 12, 1986.

Hon. JOHN D. DINGELL,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 4754, a bill that would require the appointment of the Commissioner of Food and Drugs to be subject to Senate confirmation, as ordered reported by the House Committee on Energy and Commerce on July 29, 1986. CBO expects no additional cost to the federal government or to state and local governments would result from enactment of this legislation.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes.

Sincerely,

RUDOLPH G. PENNER, *Director.*

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee makes the following statement with regard to the inflationary impact of the reported bill:

The legislation requires that the Commissioner of the Federal Food and Drug Administration (FDA) be appointed by the President and the appointment confirmed by the Senate. The legislation does not impose new regulatory burdens on the FDA, nor does it require additional appropriations. The Committee does not believe the legislation will have an inflationary impact upon the economy.

SECTION-BY-SECTION ANALYSIS

SECTION 1. APPOINTMENT OF COMMISSIONER

Chapter IX of the Federal Food, Drug and Cosmetic Act is amended by adding at the end, two new sections.

The new section, 903, provides that the Food and Drug Administration is an agency of the Department of Health and Human Services.

The new section, 904, provides that the Food and Drug Administration shall be headed by a Commissioner of Food and Drugs, who shall be appointed by the President, by and with, the advice and consent of the Senate.

SECTION 2. EFFECTIVE DATE

Section 2 provides that the amendment made by Section 1 of H.R. 4754 shall apply to appointments of Commissioners of the Food and Drug Administration made after the date of the enactment of this Act.

AGENCY VIEWS

The Committee has not received agency views on H.R. 4754.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of Rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

CHAPTER IX OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER IX—MISCELLANEOUS

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FOOD AND DRUG ADMINISTRATION

SEC. 903. The Food and Drug Administration is an agency of the Department of Health and Human Services.

APPOINTMENT OF COMMISSIONER

SEC. 904. The Food and Drug Administration shall be headed by a Commissioner of Food and Drugs who shall be appointed by the President, by and with the advice and consent of the Senate.

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